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EXAMINER
PICCONE, L

ART UNIT	PAPER NUMBER
152	14

DATE MAILED: 09/12/91

CUSHMAN, DARBY & CUSHMAN
ELEVENTH FLOOR
1615 L STREET, N.W.
WASHINGTON, DC 20036-5601

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 6/17/91 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 18 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-18 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

15.

The examiner acknowledges receipt of the amendment filed June 19, 1991.

16.

Applicant's arguments with respect to claims 1-17 are have been considered but are deemed to be moot in view of the new grounds of rejection.

17.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

18.

Claims 1-12 and 18 are rejected under 35 U.S.C. § 103 as being unpatentable over Vogelsang U.S. 3,813,384 in view of art admitted in the specification.

Vogelsang teaches azelastine in a composition that can be

administered in drops, ointments or other "usual embodiments" that are used to administer azelastine (column 6, lines 65-70). Vogelsang teaches the administration of azelastine in amounts of from 0.4 to 4 mg (column 7, line 2). Also vogelsang shows the addition of numerous pharmaceutical Adjuvants (column 43 lines 5-15). It would have been obvious to administer, the azelastine compositions of vogelsang directly to the nasal tissues or conjunctival sac to meet claims 1-4, 6-7, 9-12 because these are the areas to which medicament drops are normally applied. Claims 5, 8 and 18 would have been obvious because it is admitted in the specification that the claimed preseruahres are well known in the art and vogelsang discloses the use of adjuvant, in his compositions.

19.

Claims 13-17 are rejected under 35 U.S.C. § 103 as being unpatentable over Vogelsang U.S. 3,813,384 in view of art admitted in the specification as applied to claims 13-17 above, and further in view of in light of Barnes U.S. 158,564, Ashkenaz U.S. 2,995,308, Mendl U.S. 119,643 and Arp U.S. 2,457,024

Vogelsang discloses azelastine as an antihistamine. Vogelsand does not disclose the use of an eyedropper, a pump sprayer, an atomizer or a tube for dispensing ointment. Barnes discloses droppers for dispensing solutions. Applicant discloses the we of an eye dropper as a dispenser in claim 13.

Askenaz discloses a pump sprayer which may be used as applicant does in claim 14.

Mendl discloses an atomizer which functions in a manner similar to that disclosed on claims 15 and 16.

Arp discloses a tube for dispensing ointment as disclosed in column 17.

Claims 13-17 would have been obvious because they involve dispensing a known medication in a conventional manner.

No claim is allowed.

20.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

21.

Any inquiry concerning this communication should be directed to Louis A. Piccone at telephone number (703)-308-4431.

Piccone/mh
September 10, 1991
9-6-91

SUPERVISORY PATENT EXAMINER
ART UNIT 152